

amount of from about 25 to about 750 mg/m², and the thalidomide, or pharmaceutically acceptable salt, solvate, hydrate, or clathrate thereof, is administered in an amount of from about 50 to about 1000 mg.

4. (Amended) The method of claim 3 wherein the irinotecan, or pharmaceutically acceptable salt, solvate, hydrate, or clathrate thereof, is administered in an amount of from about 50 to about 500 mg/m², and the thalidomide, or pharmaceutically acceptable salt, solvate, hydrate, or clathrate thereof, is administered in an amount of from about 100 to about 750 mg.

5. (Amended) The method of claim 4 wherein the irinotecan, or pharmaceutically acceptable salt, solvate, hydrate, or clathrate thereof, is administered in an amount of from about 100 to about 350 mg/m², and the thalidomide, or pharmaceutically acceptable salt, solvate, hydrate, or clathrate thereof, is administered in an amount of from about 200 to about 500 mg.

6. (Amended) A method of increasing the dosage of irinotecan that can be safely and effectively administered to a patient, which comprises administering to a patient in need of such an increased dosage an amount of thalidomide, or a pharmaceutically acceptable salt, solvate, hydrate, or clathrate thereof, that is sufficient to reduce a dose-limiting adverse effect associated with the irinotecan.

7. (Amended) The method of claim 6 wherein the thalidomide, or a pharmaceutically acceptable salt, solvate, hydrate, or clathrate thereof, is administered prior to the administration of the irinotecan.

8. (Amended) The method of claim 6 wherein the thalidomide, or a pharmaceutically acceptable salt, solvate, hydrate, or clathrate thereof, is administered simultaneously with the administration of the irinotecan.

9. (Amended) The method of claim 6 wherein the thalidomide, or a pharmaceutically acceptable salt, solvate, hydrate, or clathrate thereof, is administered after the administration of the irinotecan.

12. (Amended) The method of claim 6 wherein the thalidomide, or pharmaceutically acceptable salt, solvate, hydrate, or clathrate thereof, is administered in an amount of from about 1 to about 2000 mg.

13. (Amended) The method of claim 12 wherein the thalidomide, or pharmaceutically acceptable salt, solvate, hydrate, or clathrate thereof, is administered in an amount of from about 50 to about 1000 mg.

14. (Amended) The method of claim 13 wherein the thalidomide, or pharmaceutically acceptable salt, solvate, hydrate, or clathrate thereof, is administered in an amount of from about 100 to about 750 mg.

15. (Amended) The method of claim 14 wherein the thalidomide, or pharmaceutically acceptable salt, solvate, hydrate, or clathrate thereof, is administered in an amount of from about 200 to about 500 mg.

16. (Amended) A method of increasing the therapeutic efficacy of irinotecan which comprises administering to a patient in need of such increased therapeutic efficacy an amount of thalidomide, or a pharmaceutically acceptable salt, solvate, hydrate, or clathrate thereof, that is sufficient to increase the therapeutic efficacy of irinotecan.

17. (Amended) The method of claim 16 wherein the thalidomide, or a pharmaceutically acceptable salt, solvate, hydrate, or clathrate thereof, is administered prior to administration of the irinotecan to the patient.

18. (Amended) The method of claim 16 wherein the thalidomide, or a pharmaceutically acceptable salt, solvate, hydrate, or clathrate thereof, is administered during administration of the irinotecan to the patient.

19. (Amended) The method of claim 16 wherein the thalidomide, or a pharmaceutically acceptable salt, solvate, hydrate, or clathrate thereof, is administered after administration of the irinotecan to the patient.

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